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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,145	03/11/2004	Frank H. Boehm JR.	1199-2 DIV CON	5569
28249	7590	10/31/2007		
DILWORTH & BARRESE, LLP 333 EARLE OVINGTON BLVD. SUITE 702 UNIONDALE, NY 11553			EXAMINER SWIGER III, JAMES L	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 10/31/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/798,145

Applicant(s)

BOEHM ET AL.

Examiner

James L. Swiger

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16-19 and 21-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-19 and 16-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 4/10/2007.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-19 and 21-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winslow et al. (Reference U.S Patent 6,083,225) in view of Smith (US Patent 4,862,891) and Orth et al. (US Pub 2002/0002360).

Winslow et al. (herein Winslow) disclose a device capable of performing percutaneous interbody fusion having at least at least one intervertebral disc spacer that is configured for insertion into an intervertebral disc (see Fig. 13) and a tool (82) for delivering the at least one disc spacer (col. 9, lines 13-19). A retractor is used for delivering the at least one disc spacer through one of the dilators to an intervertebral disc space. Winslow also teaches an intervertebral disc spacer that has holes (200) that may be used for bone-growth inducing substances (Col. 3, lines 19-25) and thus the use of a bone matrix substance being part of the kit is implied in its use.

Winslow discloses the claimed invention except for at least one guide needle and a plurality of dilators. Smith disclose a at least one guide needle (33) and a plurality of dilators (36-41) wherein a first dilator has an inner diameter that is slightly larger than an outer diameter of the guide needle, and each dilator having an inner diameter successively larger than an outer diameter of a previous dilator (see Fig. 7 and see Col.

5, lines 35-45) in order to dilate a passage with increased accuracy and reduced trauma. It would have been obvious to one skilled in the art at the time the invention was made to construct the kit of Winslow having at least one guide needle and a plurality of dilators in view of Smith, in order to dilate a passage with increased accuracy and reduced trauma.

Winslow discloses the claimed invention except for a package that is sterilized with the claimed instrumentation. Orth et al. teach a kit comprised in a container for holding the various kit components together, typically being a pouch, tray, box, tube, or the like. The box would have at least depressions to hold the tools in place. Additionally the box or container-like structure would inherently have at least a top or bottom surface in a way that would protect the sterilized tools. The kit components would be sterilized and maintained to sterility within the packaging [0015]. It would have been obvious to one skill in the art at the time the invention was made to construct the kit of Winslow et al. in view of Orth in order maintain sterility within the package. It is noted that all the components of the claimed invention can inherently be assembled into a kit.

### ***Response to Arguments***

Applicant's arguments with respect to claims 16-19 and 21-36 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



10/24/07

JLS



EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER